

**REMARKS**

Claims 66-100 are pending in this application. Claims 1-65, 72-77, 86-91 and 95-100 have been canceled without prejudice to or disclaimer of the subject matter contained therein. Claims 66-71, 81-82 and 84-85 have been amended. Claims 78-80 and 92 and 94 have been amended, but are withdrawn as being directed to non-elected subject matter. Claim 93 has been withdrawn as being directed to non-elected subject matter.

Applicants, by canceling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Claim 66 has been amended to recite "A molecule, comprising: a peptide represented by an isolated amino acid sequence comprising SEQ ID NO:1, the peptide optionally being capable of binding to mannosylated lipoarabinomannan (ManLAM) binding antibodies and optionally being capable of eliciting, upon immunization in a subject, production of ManLAM-binding antibodies." Support for this amendment can be found throughout the specification and claims as originally filed.

Claim 81 has been amended to recite "A kit for diagnosing mycobacterial infection in a subject, the kit comprising: an amino acid molecule comprising a peptide represented by an isolated amino acid sequence comprising SEQ ID NO:1, the peptide optionally being capable of binding to ManLAM-binding antibodies and optionally being capable of eliciting, upon immunization of a subject, production of ManLAM binding antibodies." Support for this amendment can be found throughout the specification and claims as originally filed.

Claim 82 has been amended to recite "A vaccine, comprising: an immunologically acceptable carrier; and a molecule comprising a peptide represented by an isolated amino acid sequence comprising SEQ ID NO:1, the peptide optionally being capable of binding to ManLAM-binding antibodies and optionally being capable of eliciting, upon immunization of a subject, production of ManLAM binding antibodies." Support for this amendment can be found throughout the specification and claims as originally filed.

Claims 67-71, 81-82 and 84-85 have been amended to correct minor typographical errors and to be placed in proper US claim format. Support for the amendments to claims 67-71, 81-82 and 84-85 can be found throughout the specification and claims as originally filed.

Withdrawn claims 78-80 and 92 and 94 have been amended similarly.

The specification has been amended to include a cross reference to related applications and to describe SEQ ID NOs in compliance with the requirements of 37 CFR 1.821 through 1.825.

No new matter has been added.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

***I. At page 3 of the Official Action, the specification has been objected to.***

The Examiner objects to the specification because: (1) the specification does not include a cross-reference to priority documents; and (2) pages 10 and 31 of the specification include reference to amino acid sequences that are longer than four amino acids in length.

In view of the following, these objections are respectfully traversed.

Applicants respectfully submit that the specification has been amended to include both a cross-reference to priority documents and to include SEQ ID NOs corresponding to all amino acid sequences longer than four amino acids.

Therefore, Applicants respectfully request that the Examiner reconsider and withdraw these objections.

***II. At page 2 of the Official Action, claims 82, 83, 90 and 91 have been provisionally rejected under the judicially created doctrine of obviousness type-double patenting as being unpatentable over claims 35 and 36 of co-pending US Patent Application No. 11/630,115 .***

Applicants respectfully request that the Examiner hold this rejection in abeyance until an indication of allowable subject matter in this application.

***III. At page 4 of the Official Action, claims 66 and 82 have been rejected under 35 USC § 101.***

The Examiner asserts that claims 66 and 82 do not sufficiently distinguish over a peptide or a composition comprising the same, as it exists in the natural environment.

In view of the following, this rejection is respectfully traversed.

Applicants submit that as amended, claims 66 and 82 are fully compliant with 35 USC § 101. In this regard, Applicants note that claims 66 and 82 have been amended,

in part, to recite a "molecule, comprising: a peptide represented by an isolated amino acid sequence comprising SEQ ID NO:1...." Applicants submit that the amendments to claims 66 and 82 have, therefore, obviated this rejection.

Accordingly, Applicants request that the Examiner reconsider and withdraw this rejection.

**IV. At page 5 of the Official Action, claims 66-77 and 81-91 have been rejected under 35 USC § 112, second paragraph.**

The Examiner asserts that claims 66-77 and 81-91 are indefinite for the reasons set forth in the Official Action.

Applicants note that claims 72-77 and 86-91 have been cancelled without prejudice or disclaimer. Therefore, Applicants request that the Examiner reconsider and withdraw the rejection of claims 72-77 and 86-91.

With regard to the rejection of claims 66-71, Applicants submit that, as amended, claim 66-71 are clear and definite within the meaning of 35 USC § 112. Therefore, Applicants request that the Examiner reconsider and withdraw the rejection of claims 66-71.

**V. At page 6 of the Official Action claims 66-76 and 82-90 have been rejected under 35 USC § 102(e) as being anticipated by Pompejus et al. (US Patent No. 7,273,721) as evidenced by Harlow et al. (of record).**

The Examiner asserts that Pompejus et al. as evidenced by Harlow et al. describe SEQ ID NO: 5, and therefore, anticipate claims 66-76 and 82-90.

Applicants note that claims 72-76 and 86-90 have been cancelled without prejudice or disclaimer. Therefore, Applicants request that the Examiner reconsider and withdraw the rejection of claims 72-76 and 86-90.

In view of the following, the rejection of claims 66-71 and 82-85 is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that the amendment to claims 66 and 82 have obviated this rejection. In particular, claims 66 and 82 have been amended to recite a “molecule, comprising: a peptide represented by an isolated amino acid sequence comprising SEQ ID NO:1....” Claims 67-71 and 82-85 depend, either directly or indirectly, from either claim 66 or 82.

In contrast to the pending subject matter, Applicants submit that Pompejus et al. as evidenced by Harlow et al. do not describe a peptide represented by an isolated amino acid sequence comprising SEQ ID NO: 1, as claimed. Therefore, Pompejus et al. as evidenced by Harlow et al. do not teach each and every element of the present claims.

In view of the foregoing, it is submitted that Pompejus et al. as evidenced by Harlow et al. do not teach, either expressly or inherently, each and every element of present claims 66-71 and 82-85, as required for anticipation under 35 USC § 102 (e).

**VI. At page 7 of the Official Action claims 66-73 and 82-90 have been rejected under 35 USC § 102(e) as being anticipated by Doucette-Stamm et al. (US Patent No. 6,699,703) as evidenced by of Covacci et al. (of record).**

The Examiner asserts that Doucette-Stamm et al. as evidenced by Covacci et al. describe a sequence that includes five amino acids in common with five amino acids in SEQ ID NO: 1., and therefore, anticipate claims 66-73 and 82-90.

Applicants note that claims 72-73 and 86-90 have been cancelled without prejudice or disclaimer. Therefore, Applicants request that the Examiner reconsider and withdraw the rejection of claims 72-73 and 86-90.

In view of the following, the rejection of claims 66-71 and 82-85 is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that the amendment to claims 66 and 82 have obviated this rejection. In particular, claims 66 and 82 have been amended to recite a "molecule, comprising: a peptide represented by an isolated amino acid sequence comprising SEQ ID NO: 1...." Claims 67-71 and 82-85 depend, either directly or indirectly, from either claim 66 or 82.

In contrast to the pending subject matter, Applicants submit that Doucette-Stamm et al. as evidenced by Covacci et al., at most, describe a sequence that includes five amino acids in common with five amino acids in SEQ ID NO: 1. However, Doucette-Stamm et al. as evidenced by Covacci et al. do not describe a peptide represented by an isolated amino acid sequence comprising (at least) SEQ ID NO: 1, as claimed. Therefore, Doucette-Stamm et al. as evidenced by Covacci et al. do not teach each and every element of the present claims.

In view of the foregoing, it is submitted that Doucette-Stamm et al. as evidenced by Covacci et al. do not teach, either expressly or inherently, each and every element of present claims 66-71 and 82-85, as required for anticipation under 35 USC § 102 (e).

**VII. At page 11 of the Official Action, claim 81 has been rejected under 35 USC § 103(a) as being obvious over Pompejus et al.**

The Examiner asserts that although the claimed kit is not expressly taught by Pompejus et al., the kit recited in claim 81 would have been obvious to a skilled artisan.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a

reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants respectfully submit that a *prima facie* case of obviousness has not been established because Pompejus et al. do not teach or suggest each and every limitation of the presently pending claims as required by *In re Wilson*.

Claim 81 is directed to A kit for diagnosing mycobacterial infection in a subject, the kit comprising: an amino acid molecule comprising a peptide represented by an amino acid sequence comprising SEQ ID NO: 1, the peptide optionally being capable of binding to ManLAM-binding antibodies and optionally being capable of eliciting, upon immunization of a subject, production of ManLAM binding antibodies.

In contrast to the presently pending subject matter, Pompejus et al. describes an amino acid sequence of MWYRH. However, unlike the presently claimed subject matter, Pompejus et al. do not teach or suggest a peptide represented by an isolated amino acid sequence comprising (at least) SEQ ID NO: 1, as claimed.



In this regard, Applicants note that SEQ ID NO: 1 has the following sequence: ISLTEWSMWYRH. Pompejus et al., in contrast, only describes an amino acid sequence of MWYRH. Applicants submit that nowhere in Pompejus et al. is SEQ ID NO: 1 taught or suggested. Accordingly, Applicants submit that Pompejus et al. do not render the present subject matter obvious.

In further support of Applicants position, Applicants respectfully submit that peptide fragments shorter than SEQ ID NO: 1 are significantly less active than those comprising the amino acid sequence of SEQ ID NO: 1.

In this regard, Applicants submit that the screening parameter for activity of peptides according to the present subject matter was the binding to of a potential peptide to the specific anti-ManLAM monoclonal antibody, CS40. The B11 peptide (SEQ ID NO: 1) was compared, in binding to the CS40 anti ManLAM mAb, and to a selection of peptides as follows (also provided in the following Table):

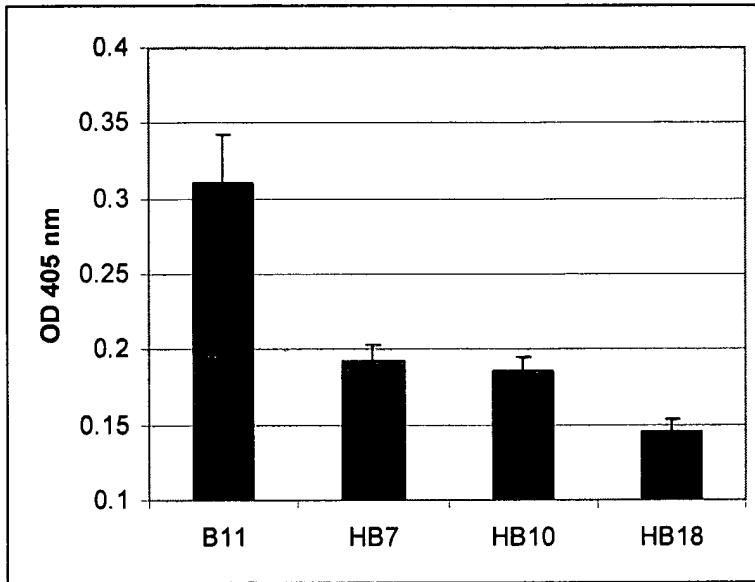
Peptide HB7: With Alanine replacement at position 1

Peptide HB 10: With Alanine replacements at positions 1-4

Peptide HB18: that does not have the Isoleucine at position 1 (10 AA instead of 11).

B11		I	S	L	T	E	W	S	M	Y	R	H
HB7		A	S	L	T	E	W	S	M	Y	R	H
HB10		A	A	A	A	E	W	S	M	Y	R	H
HB18			S	L	T	E	W	S	M	Y	R	H

The binding results are shown in the following figure.



As shown in the figure, the binding of CS40 anti ManLAM mAb decreased dramatically when the amino acids of B11 sequence were replaced. Also, the binding was lower when the first four amino acids were replaced by Alanine. Yet further, the binding was lower in peptides with replacement of the first amino acid Isoleucine and even lower when Isoleucine was deleted (10AA instead of 11AA).

Therefore, Applicants submit that all of SEQ ID NO: 1 must be present in a molecule to achieve the binding capacity of the presently claimed subject matter. Further, Applicants submit that any change in the sequence significantly affects the binding capacity of the peptide to the desired antibodies.

In view of the remarks set forth herein, it is submitted that Pompejus et al. do not render the present subject matter obvious within the meaning of 35 USC § 103(a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**VII. At page 11 of the Official Action, the claims are objected to.**

The Examiner objects to the claims for the reasons set forth in the Official Action.

Applicants respectfully submit that the objections to the claims have been rendered moot by the amended claims submitted herewith. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

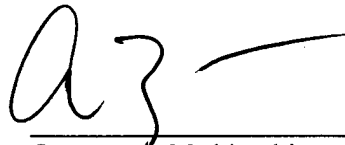
**CONCLUSION**

In view of the foregoing, Applicants submit that the application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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